The first batteryless, solar-powered cardiac pacemaker

Andreas Haeberlin, MD, PhD,[*†] Adrian Zurbuchen, MSc,[†] Sébastien Walpen, MSc,[†] Jakob Schaerer,[†] Thomas Niederhauser, PhD,[†‡] Christoph Huber, MD,[§] Hildegard Tanner, MD,[*] Helge Servatius, MD,[*] Jens Seiler, MD,[*] Heinrich Haeberlin, PhD,[‖] Juerg Fuhrer, MD,[*] Rolf Vogel, MD, PhD, MSEE[†¶]

From [*]*Department of Cardiology, Bern University Hospital and University of Bern, Bern, Switzerland,* [†]*ARTORG Center for Biomedical Engineering, University of Bern, Bern, Switzerland,* [‡]*Institute for Human Centered Engineering, Bern University of Applied Sciences, Biel, Switzerland,* [§]*Department of Cardiovascular Surgery, Bern University Hospital and University of Bern, Bern, Switzerland,* [‖]*Photovoltaics Laboratory, Bern University of Applied Sciences, Burgdorf, Switzerland, and* [¶]*Department of Cardiology, Buergerspital Solothurn, Solothurn, Switzerland.*

BACKGROUND Contemporary pacemakers (PMs) are powered by primary batteries with a limited energy-storing capacity. PM replacements because of battery depletion are common and unpleasant and bear the risk of complications. Batteryless PMs that harvest energy inside the body may overcome these limitations.

OBJECTIVE The goal of this study was to develop a batteryless PM powered by a solar module that converts transcutaneous light into electrical energy.

METHODS Ex vivo measurements were performed with solar modules placed under pig skin flaps exposed to different irradiation scenarios (direct sunlight, shade outdoors, and indoors). Subsequently, 2 sunlight-powered PMs featuring a 4.6-cm^2 solar module were implanted in vivo in a pig. One prototype, equipped with an energy buffer, was run in darkness for several weeks to simulate a worst-case scenario.

RESULTS Ex vivo, median output power of the solar module was 1963 μW/cm^2 (interquartile range [IQR] 1940–2107 μW/cm^2) under direct sunlight exposure outdoors, 206 μW/cm^2 (IQR 194–233 μW/cm^2) in shade outdoors, and 4 μW/cm^2 (IQR 3.6–4.3 μW/cm^2) indoors (current PMs use approximately 10–20 μW). Median skin flap thickness was 4.8 mm. In vivo, prolonged SOO pacing was performed even with short irradiation periods. Our PM was able to pace continuously at a rate of 125 bpm (3.7 V at 0.6 ms) for 1½ months in darkness.

CONCLUSION Tomorrow's PMs might be batteryless and powered by sunlight. Because of the good skin penetrance of infrared light, a significant amount of energy can be harvested by a subcutaneous solar module even indoors. The use of an energy buffer allows periods of darkness to be overcome.

KEYWORDS Pacemaker; Batteryless pacemaker; Batteryless pacing; Solar pacemaker; Energy harvesting; Sunlight-powered pacemaker; Pacemaker technology; Sunlight

ABBREVIATIONS IQR = interquartile range; **PM** = pacemaker

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Introduction

Contemporary pacemakers (PMs), like other active medical implanted devices, are powered by primary batteries with limited energy-storing capacity. When the battery's lifetime ends, the device needs to be replaced. PM replacements are common, accounting for more than a quarter of all PM surgery procedures.[1] They are bothersome for patients, bear the risk of complications (eg, infections, bleedings), and are costly.

To overcome the limitations of today's systems, intracorporeal energy-harvesting techniques have been proposed.[2–6] Intracorporeal energy harvesting would allow PMs to be built without primary batteries, thus reducing the number of reinterventions. However, because of major drawbacks (eg, low energy output,[2,4,5] invasive implantation procedures[3,6]), none of these approaches has been implemented successfully in cardiac PMs to date.

On the basis of theoretical calculations and bench research measurements, we recently showed that direct sunlight may be used as an alternative energy source to power PMs.[7] Sunlight can be converted into electrical energy by solar cells. Because

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near-infrared light easily penetrates the human skin, this conversion is also possible if the solar cells are implanted subcutaneously.[7,8] Just a few minutes of direct sunlight may provide enough energy to power a PM by a subcutaneous solar module for an entire day.[7] However, a key limitation of this approach is that regular exposure of a person to direct sunlight cannot be guaranteed, for several reasons. Individual lifestyle (eg, indoor workplaces), location, and climate may heavily affect daily sunlight exposure. Thus, an appropriate energy storage and management system is a key element of a sunlight-powered (or solar-powered) PM. The goal of the present study was to investigate whether subcutaneous energy harvesting is possible not only under full sunlight (as reported previously[7]) but also under real-life low-light conditions, such as in shade or indoors. Moreover, we present the first functional prototype of an implantable sunlight-powered, batteryless PM. The design of this device is presented in detail, and its functionality was tested in bench research and in vivo. In particular, we demonstrate that it is feasible to overcome prolonged periods of darkness with this novel device.

Methods

The study was structured as 3 main experiments. First, ex vivo measurements under natural ambient sunlight were performed indoors and outdoors in bench research using pig skin flaps. Second, a dedicated batteryless, sunlight-powered cardiac PM was developed, implanted in a pig, and powered by a solar module to demonstrate the acute feasibility of the concept. This PM features dedicated energy management and storage elements. In a third step, the PM was explanted and run in complete darkness to assess the long-term performance of the device in a worst-case scenario.

The trial was approved by the ethics committee of the Veterinary Department of the Canton of Bern, Switzerland, and was performed in compliance with the *Guide for the Care and Use of Laboratory Animals*.[9]

Evaluation of different light irradiation intensities (experiment 1)

Solar module

To estimate the power output of subcutaneously implanted solar cells, we placed a solar module under pig skin flaps and exposed it to natural ambient light (ex vivo experiment). The solar module consisted of 3 monocrystalline solar cells (KXOB22-12X1, IXYS Corporation, Milpitas, California), which were soldered in series and contacted on the rear side. The module was encapsulated by transparent biocompatible silicone (Elastosil RT 601, Wacker, München, Germany). This silicone's light-absorption rate from 650 to 1100 nm, that is, in the relevant spectral band, is negligible.[10]

Skin model and light exposure

The solar module was placed ex vivo under 6 different nonvital pig skin flaps (6-month-old white domestic pigs). Although nonvital, these skin flaps are a reliable model for in vivo experiments[7] with similar optical properties as human skin.[8] The pigs were purchased directly from the slaughterhouse.

The skin flaps were exposed to 3 different lighting conditions:

(1) Outdoors under direct full sunlight (skin flaps aligned orthogonally to the direction of the sun, sun elevation 65°, on a sunny spring day with clear sky conditions). Median absolute light intensity was 842 W/m^2 (interquartile range [IQR] 835–859 W/m^2; measured by a calibrated reference cell).
(2) Outdoors, in shade on the same spring day. Only indirect diffuse light fell on the skin flaps. The measured absolute light intensity was 120 W/m^2.
(3) Indoors without direct sunlight exposure on the same spring day. The measurements were performed in a meeting room (2 m from the closed windows, with a northern exposure; no artificial lights were turned on). The measured absolute light intensity was 4 W/m^2.

Power measurement

The solar module was connected to a digital multimeter (Metrahit Energy, Gossen-Metrawatt, Nürnberg, Germany). To measure the maximum available output power of the solar module at the maximum power point,[11] we varied the load resistor using a resistor cascade board (SE40, Schärer Elektronik AG, Sarmenstorf, Switzerland). The maximum available output power was normalized to a standardized solar irradiation of 1 kW/m^2.

In vivo implantation of the sunlight-powered, batteryless PM (experiment 2)

PM description

We developed 2 custom-built batteryless, single-chamber PM prototypes. Both were powered by the solar module as described above and featured a 4.6-cm^2 solar module. An energy management system featuring an ultra-low-power boost converter (BQ25504, Texas Instruments, Dallas, Texas) and including a maximum power point tracker[11] allowed efficient energy harvesting for different irradiation scenarios (Figure 1). The measured housekeeping power of the electronic circuit was 7.15 μW. The energy was stored in a 100-μF ceramic capacitor (prototype 1; MC0402X104K100CT, Multicomp, Farnell element14, Leeds, United Kingdom) or a 9-mA · h lithium-ion polymer accumulator, respectively (prototype 2; GE020815, GE Battery, Shenzen, China). The entire electronics were embedded in a translucent biocompatible silicon housing (Elastosil RT 601, Wacker, München, Germany). The device's dimensions were 30 × 35 × 6 mm (volume 6.3 cm^3; weight of prototype 1, 11.5 g; weight of prototype 2, 11.1 g). It was equipped with a conventional IS-1 header (Figure 2) and operated in asynchronous SOO mode. A reed switch enabled inhibition of the device (magnet mode OOO) .

Device implantation

The acute animal study was performed on a 60-kg female domestic pig under inhalation anesthesia (isoflurane in oxygen [1.6 %] and fentanyl [5–10 μg/kg per hour]). Both

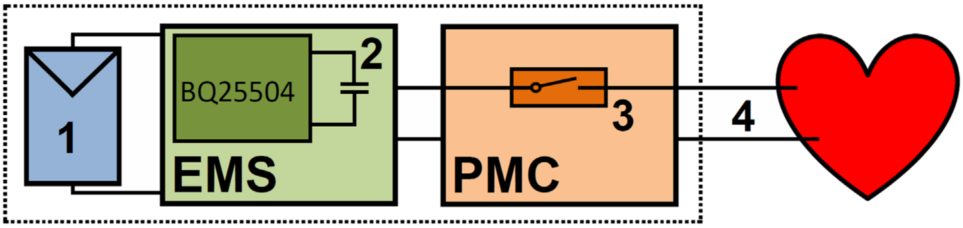

Figure 1 Schematic of the sunlight-driven pacemaker. The translucent housing (dotted square) contains the solar module (1), the energy management system (EMS), and the pacemaker circuit (PMC). The EMS features a boost converter with a maximum power point tracker (BQ25504) and stores the energy in a capacitor or accumulator (2). The PMC contains a square pulse generator (3) and delivers the pacing pulse via the pacing electrodes (4).

PM prototypes were tested one after the other for 30 minutes each. A conventional bipolar active PM lead (Safio S60, Biotronik, Berlin, Germany) was implanted first via the right jugular vein in the right ventricle (prototype 1) and, after removal of prototype 1, in the right atrium (prototype 2). Sensing, impedance, and pacing thresholds were measured with a CareLink programmer (model 2090, Medtronic, Minneapolis, Minnesota). The PM lead was connected to the IS-1 header of the PM, which was then implanted subcutaneously into a pocket in the right lateral neck of the pig.

The covering skin layer of prototype 1 (fully discharged capacitor) was subsequently irradiated by a calibrated solar simulator[7] that mimicked full sunlight outdoors to demonstrate that pacing was feasible. We stimulated the pig's heart at a higher rate than its intrinsic heart rate and recorded the electrocardiogram using a 12-lead electrocardiography recorder (AT-104 PC, Schiller AG, Baar, Switzerland).

PM prototype 2 was implanted subcutaneously at the same location as prototype 1. The accumulator of prototype 2 cannot be completely discharged because of the design principle of a lithium-ion polymer accumulator and a programmed safety feature of the energy management system. Thus, the accumulator of prototype 2 was already charged, and pacing could be performed without irradiation just to demonstrate the functionality of the prototype.

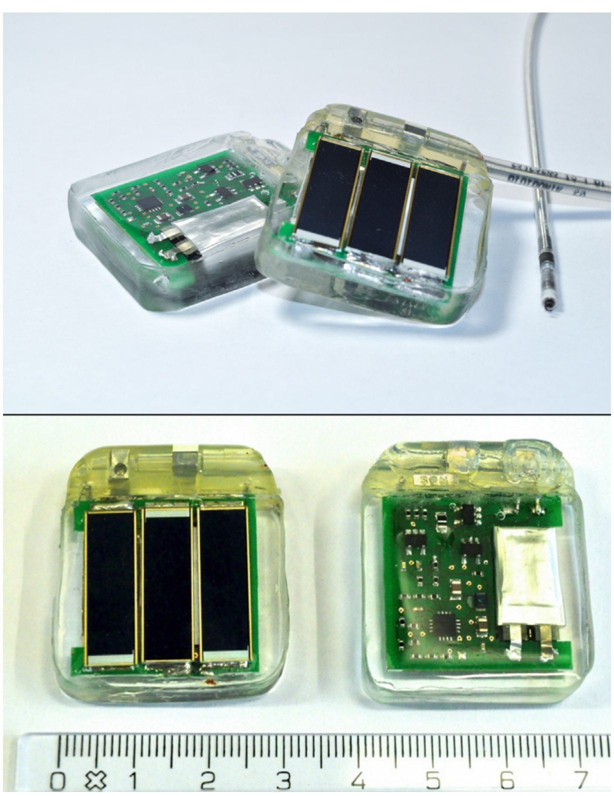

Figure 2 The sunlight-driven pacemaker prototype 2 (2 devices are shown). **Top**, A conventional bipolar active pacemaker lead (Safio S60, Biotronik) is attached via an IS-1 header. **Bottom**, The back side of the device reveals a small lithium-polymer accumulator (visible as silver part of the device on the right). The energy source for the device, a solar module, can be seen in the frontal view (device on the left). The dimensions of the device are 30 × 35 × 6 mm.

Long-term bench testing of the sunlight-powered, batteryless PM (experiment 3)

The long-term absence of sunlight is a worst-case scenario for solar PMs. To assess the long-term performance of the device under such circumstances in vivo, a pig would have to be kept in complete darkness for many weeks. This was not possible because of animal welfare concerns and was not approved by the responsible veterinary department. Thus, we assessed the behavior of the device in bench research testing in complete darkness, which additionally ensured an unfavorable high-power consumption of the device. First, the accumulator of prototype 2 was fully charged; subsequently, the device was kept in complete darkness to pace SOO at 125 bpm with 3.7 V at 0.6 ms over a 500-Ω load resistor (resistor cascade board SE40, Schärer Elektronik). The accumulator voltage was checked periodically to monitor the discharge over time.

Statistical analysis

R version 3.1.1 for Windows was used for statistical analysis. Output power of the solar module was reported as median values with IQR. A Spearman rank correlation coefficient ($\rho_{Spearman}$) was calculated to assess the correlation of light intensity and output power of the solar module. $P \leq .05$ was considered significant.

Results

Evaluation of different light irradiation intensities

We measured the solar module output power under 6 different skin flaps (median thickness 4.8 mm [IQR 4.3–5.3 mm]) outdoors in full sunlight, outdoors in shade, and indoors (Figure 3). Under full sunlight outdoors, median

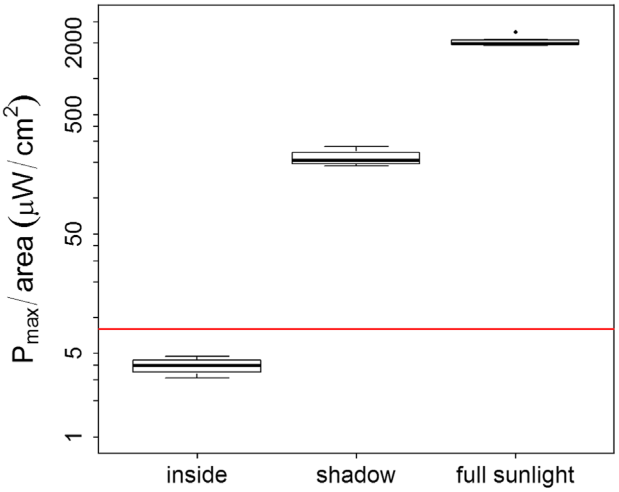

Figure 3 Boxplots illustrating the power output of the solar module per square centimeter under different irradiation conditions (note the logarithmic y-axis). The red horizontal line indicates the required housekeeping power of a modern pacemaker.

output power of the solar module was 1963 $\mu W/cm^2$ (IQR 1940–2107 $\mu W/cm^2$). Outdoors in shade, we measured a median output of 206 $\mu W/cm^2$ (IQR 194–233 $\mu W/cm^2$), and indoors, 4 $\mu W/cm^2$ (IQR 3.6–4.3 $\mu W/cm^2$). The output power of the solar module correlated with light intensity ($\rho_{Spearman} = 0.94$, $P < .0001$).

In vivo implantation of the sunlight-powered, batteryless PM

Both PM prototypes were implanted in the right lateral neck of the pig at an implantation depth of 2.4 mm (Figure 4). During irradiation (mimicking full direct sunlight) of the module-covering skin layer, we measured an output power of 6747 $\mu W/cm^2$.

The impedance of the endocardial pacing lead was 1279 Ω, the right ventricular pacing threshold was 1.0 V at 0.5 ms, and the sensed R-wave amplitude was 9.8 mV. A light flicker from the solar simulator that lasted only 0.3 second fully charged the capacitor of prototype 1, and VOO pacing at 4.0 V at 0.6 ms was feasible at 130 bpm for several seconds (Online Supplemental Video).

Subsequently, we implanted prototype 2 (equipped with the precharged accumulator). The PM lead was implanted in the low right atrium (lead impedance 532 Ω, pacing threshold 0.6 V at 0.5 ms, and sensed P-wave amplitude 1.9 mV), and AOO pacing was performed successfully using the same pacing parameter settings (Figure 5).

Long-term bench test of the sunlight-powered, batteryless PM

Prototype 2, which was used for the long-term test in complete darkness, had an accumulator voltage of 4.08 V at the beginning of the test (fully charged). In this test scenario, the PM was not able to harvest any energy from the solar module; thus, we observed a continuous drop in the voltage of the accumulator (Figure 6). After 40 days of continuous SOO pacing, the voltage dropped significantly. At that time, the accumulator's energy was exhausted, and the device was not able to pace any more.

Discussion

The dependency on batteries is a key limitation of any electronic implant such as PMs. In this study, we present an alternative

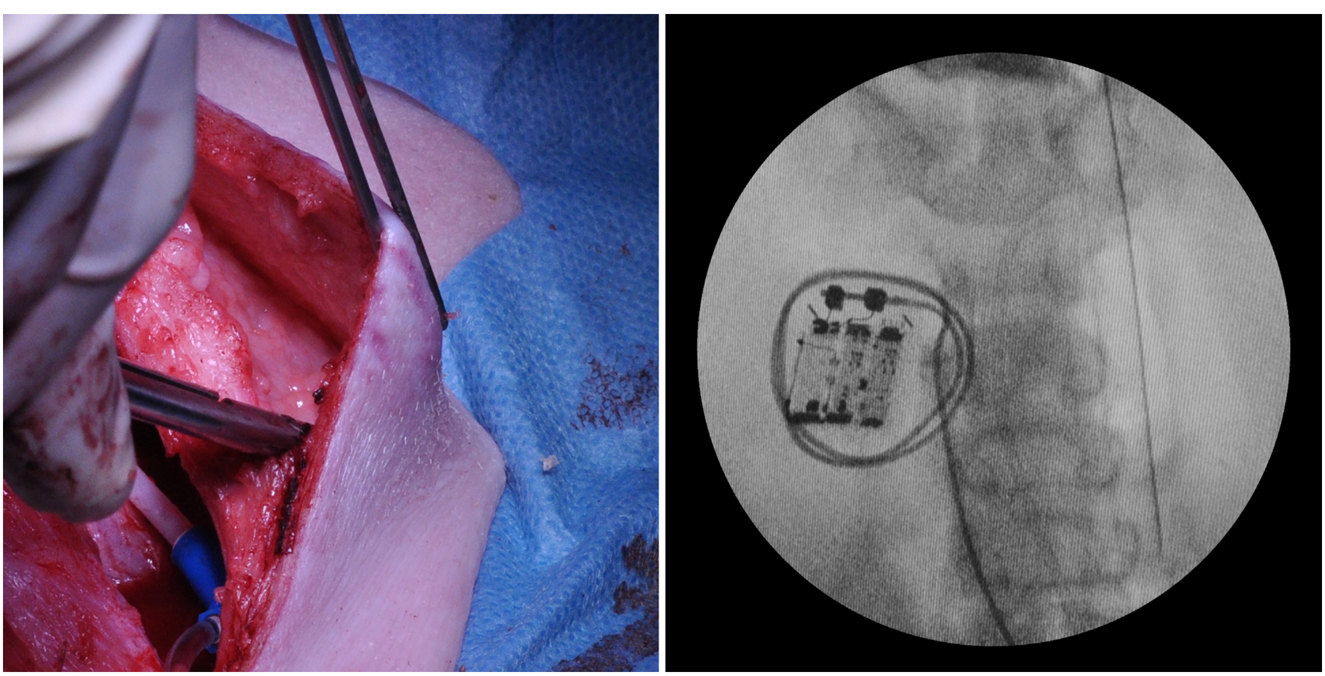

Figure 4 Preparation of the pocket for the device (**left**). Underneath the pocket, the proximal end of a conventional sheath can be seen. This sheath has previously been inserted in the right external jugular vein and will be the access site for the pacing lead. The fluoroscopy image (**right**) shows a posterior-anterior projection of the implanted device with the lead entering the right external jugular vein.

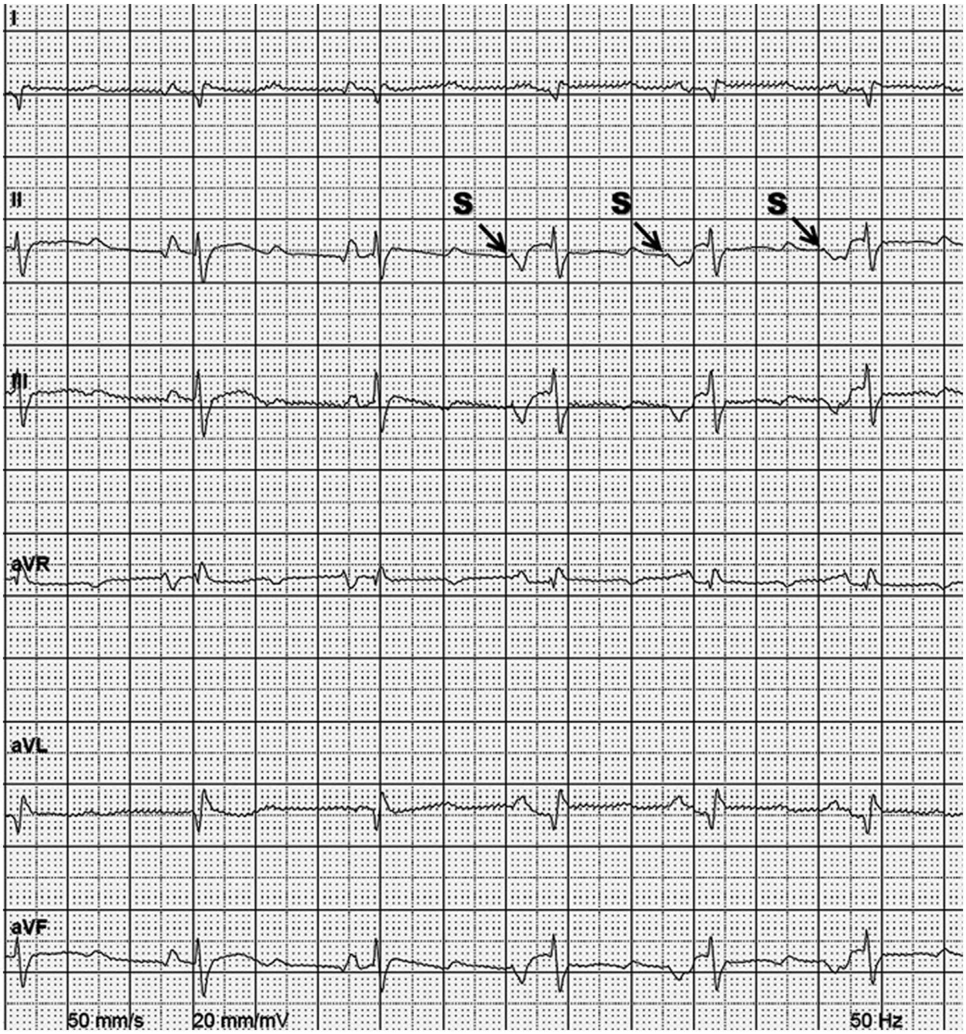

Figure 5 Electrocardiogram recorded after implantation of the sunlight-driven pacemaker (prototype 2 with accumulator) at the beginning of AOO pacing. Pacemaker stimuli are indicated (S).

energy supply for a PM using ambient light as the energy source. We present the first fully functional, batteryless, sunlight-powered, single-chamber PM, which was implanted in vivo and is capable of dealing with real-life low-light conditions.

Evaluation of different light irradiation intensities

Skin has an optical window for near-infrared light[8] that allows a subcutaneous solar cell to harvest a considerable amount of energy. Under full direct sunlight exposure, the measured output power is in the range of 2000 μW/cm^2, depending on the thickness of the covering skin layer.[7] These results are in line with theoretical calculations and preliminary results we published previously.[7] For comparison, the power consumption of a contemporary PM is approximately 10–40 μW, depending on pacing frequency, pacing amplitude, and pacing mode, among other factors. Therefore, direct, full sunlight exposure for just a few minutes may provide enough energy to pace a heart for an entire day.[7] However, the time a person is exposed to direct sunlight may be relatively short, and the time spent indoors or in shade may be much longer. Moreover, full direct sunlight exposure cannot be guaranteed because of poor weather conditions or individual lifestyle (eg, working indoors). In this study, we show for the first time that in shade and even indoors without direct sunlight, it is still possible to harvest a considerable amount of energy from ambient light. These tests

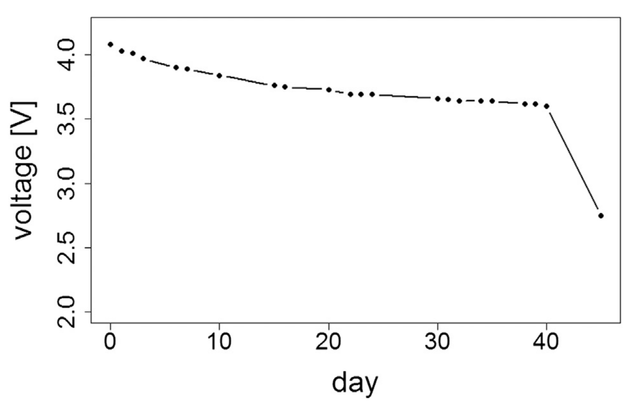

Figure 6 Accumulator voltage trend of the pacemaker prototype 2 during continuous pacing in complete darkness. The implemented accumulator guarantees full functionality of the device for more than 1 month without any external energy input from ambient light.

may better reflect real-life conditions than results reported previously.[7]

Typically, observed light intensities indoors are much lower than under full sunlight outdoors. Moreover, solar cells also exhibit a reduced conversion efficiency.[12] Thus, instead of a few thousand microwatts, a few microwatts per square centimeter may be expected indoors by a subcutaneously implanted solar module (Figure 3), which was confirmed by our measurements. Although indoor conditions alone are therefore hardly sufficient to power a sunlight-powered PM for a long time, such low-light conditions may nevertheless provide additional energy, decreasing the rapid energy-storage depletion. Under indoor conditions, 4 cm^2 of a solar module with 4 $\mu W/cm^2$ surface power density, as our prototypes have indoors, would allow the harvesting of 16 μW, which is approximately twice the housekeeping power consumption of a modern PM.[13]

If indoor lamps are switched on, one may intuitively expect an even higher power output by a solar module. Although experiments with indoor lamps were beyond the scope of this study, we would like to discuss theoretically what might be expected if indoor light sources would have been used. For physical reasons, only conventional halogen or incandescent lamps emit a continuous spectrum that contains harvestable near-infrared light. In contrast, fluorescent lamps emit only light of discrete spectral wavelengths in the visual part of the spectrum,[14] which may not be harvestable by a subcutaneous solar cell because these spectral lengths are absorbed in the skin.

In vivo implantation of the sunlight-powered, batteryless PM

As may have been expected from theoretical calculations[7] and the bench research measurements described above, we harvested >6700 $\mu W/cm^2$ during the in vivo experiment. This amount of power is several hundred times more than the mean power consumption of a commercially available PM. In other words, a 1-cm^2 subcutaneous solar module exposed to direct sunlight for 1 minute provides enough energy to pace a heart for several hours. This was illustrated by a short light flicker, which provided enough energy for prolonged pacing (Online Supplemental Video).

To overcome intermittent periods of darkness and store as much energy as possible during phases of direct sunlight irradiation, a rechargeable energy storage and energy management system are required. We used a lithium-ion accumulator because it provides high energy density and long life cycles,[15] which are of particular importance because accumulators may deteriorate over time.

Overcoming the need for primary batteries allows the device volume to be reduced. The battery accounts for approximately 50% of the volume of a contemporary PM.

Long-term bench test of the sunlight-powered, batteryless PM

Because of its unusual concept, a batteryless, sunlight-powered PM depends on external energy input, that is, ambient light. A regular daily input cannot be guaranteed, and this dependency is a key safety issue that has not been addressed to date.[7] We showed that a relatively small 9 mA · h accumulator may offer autonomy, that is, guarantee a power supply even in the complete absence of any light (no energy input at all for 1½ months) (Figure 6). This is a worst-case scenario, because even indoors, energy is harvestable, as we have seen previously; however, the size of the energy buffer we implemented may not be large enough, because autonomy for even longer time periods may be desired for safety reasons.

A sunlight-powered, batteryless PM: a technical outlook

An article on the feasibility of sunlight-driven pacing using an external pulse generator has been published recently[7]; however, the concept has neither been implemented nor tested in a single implantable device. The present manuscript is the first report on a fully implantable sunlight-powered, batteryless PM. We present encouraging results that this device is also able to overcome a worst-case scenario (prolonged darkness). The concept of a PM powered by solar light offers some major advantages. Ambient light is ubiquitous, and solar cells are an established technique with well-known long-term behavior, and they do not contain mechanically active parts, unlike other energy-harvesting approaches.[3,6]

To guarantee high solar irradiation, we suggest device implantation in the lateral neck. As mentioned previously, the energy conversion efficiency of a subcutaneous solar module depends on the implantation depth. Thus, the patient's skin thickness (eg, a massive subcutaneous fat layer) negatively affects the power output. It may be tempting to minimize the implantation depth surgically to maximize power output. On the other hand, the implantation depth should not be too shallow, or the risk of skin erosion will be increased. Although the lateral neck is a delicate implantation site from a surgical viewpoint, the abandonment of a primary battery may allow the device size to be reduced dramatically. In the future, device size and associated discomfort or foreign body reactions may be reduced further by using flexible solar cells[16] and ultrathin device packaging layers.[17] Furthermore, the device should provide a safety feature such as an alarm to alert patients if the battery voltage level becomes critically low.

Study Limitations

We did not test the concept of sunlight-powered pacing in humans. However, pig skin flaps and human skin have similar optical properties,[8] although long-term effects such as scarring and encapsulation cannot be studied with this approach. Moreover, in vivo, a short-term power output decrease (eg, due to subcutaneous blood collection around the device) may occur, although this was not observed in this study, likely because of the short stay in vivo. In addition, it is unclear how human garments would affect the proposed energy collection system.

The indoor and outdoor measurements provide evidence that a relatively large amount of energy is harvestable by a subcutaneous solar module. Nevertheless, it is difficult to standardize such experimental conditions because of their dependency on many parameters (eg, season, daytime, geographic location). Some of those parameters cannot be controlled experimentally (eg, light reflection by clouds). Moreover, and particularly for a realistic indoor scenario, some parameters must be chosen arbitrarily (eg, distance to windows, their number and size, and colors of wall/furniture). Solar simulators of such low-light conditions that feature correct spectral representation in the near-infrared range are not available. Nevertheless, we believe that our indoor scenario is realistic, because the irradiance measured by a reference cell was similar to other published "realistic" indoor light intensities.[18]

The animal experiment was an acute study only. Further experiments to prove the efficacy of the device are required and should ideally include long-term testing in vivo with alterations of real-life light conditions and regular battery voltage checks.

Conclusion

In our study, we introduce the first batteryless, sunlight-powered PM, which was successfully tested in vivo and was able to overcome intermittent periods of complete darkness. It is powered by a subcutaneously implanted solar module, which continuously harvests a significant amount of energy under direct sunlight, as well as in shade or indoors. Thus, future PMs might be batteryless and powered by ubiquitous ambient light.

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Appendix

Supplementary data

Supplementary data associated with this article can be found in the online version at http://dx.doi.org/10.1016/j.hrthm.2015.02.032.

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CLINICAL PERSPECTIVES

In this article, we present a novel pacemaker (PM) technology. Contemporary pacemakers are powered by primary batteries. PM replacements because of battery depletion are common and costly and bear the risk of complications. We propose a method to power PMs using solar cells to avoid the use of primary batteries. Transcutaneous sunlight may be converted by subcutaneous solar cells into electrical energy to power a PM circuit. This approach would allow batteryless PMs to be designed; thus, PM replacements could be avoided and the associated risks could be overcome. Batteryless PMs could be developed. However, to successfully introduce a method that overcomes the need for primary batteries, major efforts must be made by the device industry. In particular, safety concerns need to be addressed (eg, what if almost no sunlight is available for several months?). Moreover, to assess the long-term performance of a solar PM, outdoor (and preferably in vivo) studies are required.